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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/772,774	02/04/2004	Bjame Due Larsen	50412/018009	3539

21559 7590 06/26/2006

CLARK & ELBING LLP  
101 FEDERAL STREET  
BOSTON, MA 02110

EXAMINER

TELLER, ROY R

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 06/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/772,774	LARSEN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Roy Teller	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 February 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,4-9,12,13,15,18-28,31-113 and 138-171 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) See Continuation Sheet are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

Continuation of Disposition of Claims: Claims subject to restriction and/or election requirement are 1,2,4-9,12,13,15,18-28,31-113 and 138-171.

## **DETAILED ACTION**

### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 2, 4-9, 12, 13, 15, 18-28, 31-35, 37-39, 50, 51, 56, 57, 163, 164, 166, - 171, drawn to a compound having the general formula I, classified in class 514, subclass 2.
- II. Claims 41-49, 52-64, 81-89, 90-97, drawn to a compound of the general formula XII, classified in class 514, subclass 2.
- III. Claims 65-66, drawn to a compound having the formula 2, classified in class 514, subclass 2.
- IV. Claims 67-68, drawn to a compound having the formula 3, classified in class 514, subclass 2.
- V. Claims 69-70, drawn to a compound having the formula 8, classified in class 514, subclass 2.
- VI. Claims 71-72, drawn to a compound having the formula 6, classified in class 514, subclass 2.
- VII. Claims 73-74, drawn to a compound having the formula 9, classified in class 514, subclass 2.
- VIII. Claims 75-76, drawn to a compound having the formula 10, classified in class 514, subclass 2.

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- IX. Claims 77-78, drawn to a compound having the formula 11, classified in class 514, subclass 2.
- X. Claims 79-80, drawn to a compound having the formula 12, classified in class 514, subclass 2.
- XI. Claims 98-104, a compound having the general formula XVI, classified in class 514, subclass 2.
- XII. Claims 105-106, a photo labile derivative of a compound of formula I, XII, XIII, XIIIa, XIV, XV or XVI, classified in class 514, subclass 2.
- XIII. Claims 107-108, a thermo labile derivative of a compound of formula I, XII, XIII, XIIIa, XIV, XV or XVI, classified in class 514, subclass 2.
- XIV. Claim 109, a compound of formula I, XII, XIII, XIIIa, XIV, XV or XVI, having an antiarrhythmic effect, classified in class 514, subclass 2.
- XV. Claims 110-112, a pharmaceutical composition comprising a compound of of formula I, XII, XIII, XIIIa, XIV, XV and XVI and formulae 2-12, classified in class 514, subclass 2.
- XVI. Claim 113, a method of increasing gap junctional intercellular communication, classified in class 514, subclass 2.
- XVII. Claims 138-139, a method of treatment of arrhythmia, classified in class 514, subclass 2.
- XVIII. Claim 140, a method of antithrombotic treatment, classified in class 514, subclass 2.

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- XIX. Claim 141, a method of treatment of osteoporosis, classified in class 514, subclass 2.
- XX. Claim 142, a method of treating or preventing bone loss, classified in class 514, subclass 2.
- XXI. Claim 143, a method of treatment of joint disease, classified in class 514, subclass 2.
- XXII. Claim 144, 160, a method of treatment of cancer, classified in class 514, subclass 2.
- XXIII. Claim 145, a method of treatment of wounds, classified in class 514, subclass 2.
- XXIV. Claim 146, a method of treatment of ulcers, classified in class 514, subclass 2.
- XXV. Claim 147, a method of treatment for hypertension, classified in class 514, subclass 2.
- XXVI. Claim 148, a method of preventing ischemic brain damage, classified in class 514, subclass 2.
- XXVII. Claim 149, 158, a method of treating cataracts, classified in class 514, subclass 2.
- XXVIII. Claim 150, a method of treating deafness, classified in class 514, subclass 2.
- XXIX. Claim 151, a method of treating G.I. motility disorders, classified in class 514, subclass 2.
- XXX. Claim 152, a method of treating female infertility, classified in class 514, subclass 2.
- XXXI. Claim 153, a method of induction of labour, classified in class 514, subclass 2.

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XXXII. Claim 154, a method of treatment of male infertility, classified in class 514, subclass 2.

XXXIII. Claim 155, a method of improving glucose tolerance, classified in class 514, subclass 2.

XXXIV. Claim 156-157, a method of treating disease, classified in class 514, subclass 2.

XXXV. Claim 159, a method of treating the cornea, classified in class 514, subclass 2.

XXXVI. Claim 161-162, a method of treatment of glucose and oxygen deprivation of cells, classified in class 514, subclass 2.

The inventions are distinct, each from the other, because of the following reasons:

Inventions of groups I-XIII and XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are drawn to different chemical structures, each chemical structure being patentable distinct.

Inventions in groups XIV and XVI-XXXVI are directed to related processes. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation,

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function, or effect. See MPEP § 806.05(j). In the instant case, the methods are related, but medicaments would need to be different forms, dosage, etc. for each disease.

Inventions of groups I-XIII and XV and groups XIV and XVI-XXXVI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the process of use can be practiced with another materially different product, i.e., can treatment diseases with different medicaments.

No matter which group is elected, a further election of species is required.

This application contains claims directed to the following patentably distinct species of the claimed invention:

Select **one** formula/compound from formulas I, XII, XIII, XIIIa, XIV, XV, XVI, formulas 2-12. Select one SEQ ID NO for the chosen compound/ formula. All are patentably distinct due to the different structures of each. Each species would require a different structure search.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all



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claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to

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retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Because these inventions are distinct for the reasons given above and since they have acquired a separate status in the art as shown by their divergent subject matter, and/or are separately and independently searched, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirements be traversed (37 CFR 1.143).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is 571-272-0971. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm.

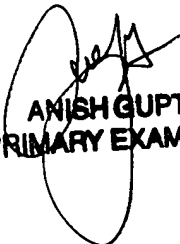
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecila Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-272-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RT  
1654  
6/22/06

RT

  
6/23/06  
**ANISH GUPTA**  
**PRIMARY EXAMINER**